

## § 178.3930

with any applicable specifications prescribed by such regulation.

[42 FR 14609, Mar. 15, 1977, as amended at 48 FR 238, Jan. 4, 1983; 49 FR 10113, Mar. 19, 1984; 49 FR 29579, July 23, 1984; 50 FR 36874, Sept. 10, 1985; 52 FR 10223, Mar. 31, 1987; 54 FR 6124, Feb. 8, 1989; 54 FR 24899, June 12, 1989; 56 FR 55456, Oct. 28, 1991; 57 FR 23953, June 5, 1992; 58 FR 17513, Apr. 5, 1993; 64 FR 47110, Aug. 30, 1999]

### § 178.3930 Terpene resins.

The terpene resins identified in paragraph (a) of this section may be safely used as components of polypropylene film intended for use in contact with food, and the terpene resins identified in paragraph (b) of this section may be safely used as components of polyolefin film intended for use in contact with food;

(a) Terpene resins consisting of the hydrogenated polymers of terpene hydrocarbons obtainable from sulfate turpentine and meeting the following specifications: Drop-softening point of 118°–138 °C; iodine value less than 20.

(b) Terpene resins consisting of polymers of beta-pinene and meeting the following specifications: Acid value less than 1; saponification number less than 1; color less than 4 on the Gardner scale as measured in 50 percent mineral spirits solution.

### § 178.3940 Tetraethylene glycol di-(2-ethylhexoate).

Tetraethylene glycol di-(2-ethylhexoate) containing not more than 22 parts per million ethylene and/or diethylene glycols may be used at a level not to exceed 0.7 percent by weight of twine as a finish on twine to be used for tying meat provided the twine fibers are produced from nylon resins complying with §177.1500 of this chapter.

### § 178.3950 Tetrahydrofuran.

Tetrahydrofuran may be safely used in the fabrication of articles intended for packaging, transporting, or storing foods, subject to the provisions of this section.

(a) It is used as a solvent in the casting of film from a solution of polymeric resins of vinyl chloride, vinyl acetate, or vinylidene chloride that have been polymerized singly or copolymer-

## 21 CFR Ch. I (4–1–01 Edition)

erized with one another in any combination, or it may be used as a solvent in the casting of film prepared from vinyl chloride copolymers complying with §177.1980 of this chapter.

(b) The residual amount of tetrahydrofuran in the film does not exceed 1.5 percent by weight of film.

## PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

### Subpart A [Reserved]

### Subpart B—Radiation and Radiation Sources

#### Sec.

179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

179.25 General provisions for food irradiation.

179.26 Ionizing radiation for the treatment of food.

179.30 Radiofrequency radiation for the heating of food, including microwave frequencies.

179.39 Ultraviolet radiation for the processing and treatment of food.

179.41 Pulsed light for the treatment of food.

### Subpart C—Packaging Materials for Irradiated Foods

179.45 Packaging materials for use during the irradiation of prepackaged foods.

AUTHORITY: 21 U.S.C. 321, 342, 343, 348, 373, 374.

SOURCE: 42 FR 14635, Mar. 15, 1977, unless otherwise noted.

### Subpart A [Reserved]

### Subpart B—Radiation and Radiation Sources

#### § 179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

Sources of radiation for the purposes of inspection of foods, for inspection of packaged food, and for controlling food processing may be safely used under the following conditions:

(a) The radiation source is one of the following:

(1) X-ray tubes producing X-radiation from operation of the tube source at a voltage of 500 kilovolt peak or lower.

(2) Sealed units producing radiations at energy levels of not more than 2.2 million electron volts from one of the following isotopes: Americium-241, cesium-137, cobalt-60, iodine-125, krypton-85, radium-226, and strontium-90.

(3) Sealed units producing neutron radiation from the isotope Californium-252 (CAS Reg. No. 13981-17-4) to measure moisture in food.

(b) To assure safe use of these radiation sources:

(1) The label of the sources shall bear, in addition to the other information required by the Act:

(i) Appropriate and accurate information identifying the source of radiation.

(ii) The maximum energy of radiation emitted by X-ray tube sources.

(2) The label or accompanying labeling shall bear:

(i) Adequate directions for installation and use.

(ii) A statement that no food shall be exposed to radiation sources listed in paragraph (a) (1) and (2) of this section so as to receive an absorbed dose in excess of 10 grays.

(iii) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(3) of this section so as to receive an absorbed dose in excess of 2 milligrays.

[42 FR 14635, Mar. 15, 1977, as amended at 48 FR 46022, Oct. 11, 1983; 61 FR 14246, Apr. 1, 1996; 64 FR 69191, Dec. 10, 1999]

**§ 179.25 General provisions for food irradiation.**

For the purposes of §179.26, current good manufacturing practice is defined to include the following restrictions:

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of part 110 of this chapter and other applicable regulations.

(b) Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use.

(c) Packaging materials subjected to irradiation incidental to the radiation treatment and processing of pre-packaged foods shall comply with §179.45.

(d) Radiation treatment of food shall conform to a scheduled process. A scheduled process for food irradiation is a written procedure that ensures that the radiation dose range selected by the food irradiation processor is adequate under commercial processing conditions (including atmosphere and temperature) for the radiation to achieve its intended effect on a specific product and in a specific facility. A food irradiation processor shall operate with a scheduled process established by qualified persons having expert knowledge in radiation processing requirements of food and specific for that food and for that irradiation processor's treatment facility.

(e) A food irradiation processor shall maintain records as specified in this section for a period of time that exceeds the shelf life of the irradiated food product by 1 year, up to a maximum of 3 years, whichever period is shorter, and shall make these records available for inspection and copy by authorized employees of the Food and Drug Administration. Such records shall include the food treated, lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

(Approved by the Office of Management and Budget under control number 0910-0186)

[51 FR 13399, Apr. 18, 1986]

**§ 179.26 Ionizing radiation for the treatment of food.**

Ionizing radiation for treatment of foods may be safely used under the following conditions:

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.

(2) Electrons generated from machine sources at energies not to exceed 10 million electron volts.